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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/205,251	12/04/1998	IRVING K. ARENBERG	INTRUS-4	8010

7590

12/20/2002

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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/205,251

Applicant(s)

ARENBERG ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 7-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3-4,6,20,22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Peterson (U.S. Patent No.4,472,394).

Manning et al. disclose the invention substantially as claimed. Manning et al. disclose a drug delivery unit comprised of a biocompatible polymersupport and at least one pharmacologically active agent that is placed such that it substantially contacts the round membrane of the middle ear. This would encompass the being in direct contact or against and "at least partially in said round window niche". With respect to the

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location of the drug delivery unit, it is disclosed on page 1, lines 19-21 that "access to the inner ear tissue regions is typically through a variety of structures including the round window membrane "... etc. That would narrow it to the location between the tympanic membrane and the round window that is the location of the round window niche since it is also disclosed that the drug delivery unit is in contact with the round membrane of the middle ear. Manning et al. teach that the device provides extended release. See page 4, lines 5-20 and abstract. On page 7, lines 7-12. Manning disclose the drug concentration can be varied over broad limits and is chosen depending upon solubility , pharmacological activity, desirable effect of the end product , patient size and weight all factors know to those skilled in the art. As for the language of the "the biocompatible polymer" it is well known in the art that that would be a synthetic as opposed to a "biopolymer" which is naturally occurring. However, Manning does not disclose the specific time period of greater than a month. Peterson teaches implanting a pellet/ ruminant beneath the ear for extended controlled release of the active ingredient over a period of 60 days to 210 days. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the period of release of the drug of Manning et al. with a period of greater than a month as taught by Peterson in order to provide uniform extended release depending on the parameters (such as weight of patient, type of drug, solubility of drug, etc.) required for a dosing regiment. Further lacking any criticality or unexpected results, it would have been obvious to modify the time period since slow release and controlled release is well

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known in the medical arts when treating the patients with respect to severity of the disease and patient's medical history.

Claims 1-2,4-5,20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Peterson (U.S. Patent No 4,472,394) and further in view of Husmann et al. (See Hearing Research, Round window administration of gentamicin: a new method for the study of ototoxicity of cochlear hair cells).

Manning et al. in view of Peterson teach all the limitations of the claims except the spaced apart limitation of the drug delivery unit from the round window membrane. See above. Hussman et al. teach and suggest drug delivery units placed and spaced apart from the round window membrane in the analogous art of drug delivery. Hussman et al. disclose a drug delivery unit placed in a desired location within the round window niche. Specifically, it is disclosed that the unit can be placed in the middle ear above or below the columella or in the middle ear directly on the membrane covering the round window, which would encompass the round window niche of the subject. (See 2.2.2.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings and suggestions of Hussman et al. to vary the location of the drug delivery unit spaced apart or in direct contact with the round window membrane because Hussman shows the knowledge generally available to one of ordinary skill in the art with respect to varying the location and placing of the drug delivery unit in the middle ear. The placing of the drug delivery unit in spaced apart and in contact with the middle ear would further bring about a more encompassing research study.

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Response to Arguments

With respect to applicant's arguments, the Examiner is not persuaded since applicant's specification discloses no criticality to the time period. Applicant's specification discloses a time period ranging from a few hours to many months.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


LoAn H. Thanh
Examiner
Art Unit 3763

LT
December 18, 2002


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700